UCONN
UNIVERSITY OF CONNECTICUT

DATE: August 15, 2017

TO: Laura K. M. Donorfio, Ph.D.
Marina Vracevic, MA, Student Investigator
HDFS

FROM: Pamela I. Erickson, Ph.D. PIE | JM
Chair, Institutional Review Board
FWA# 00007125

RE: Protocol #: H17-105, "Exploring Perceptions of Personhood of a Spouse in the Early Stage of Dementia"
Please refer to the Protocol# in all future correspondence with the IRB.
Funding Source: Unfunded
Approval Period: From: **August 15, 2017** ***Valid Through:*** **August 15, 2018**
"Expiration Date"

On May 11, 2017 the Institutional Review Board (IRB) reviewed the above-referenced research study by expedited review and determined that modifications were required to secure approval. Those requirements have been met, and the IRB granted approval of the study on August 15, 2017. The research presents no more than minimal risk to human subjects and qualifies for expedited approval under category # 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Enclosed are the validated consent forms, which are valid through August 15, 2018. **A copy of the approved, validated and stamped consent form (with the IRB's stamp) must be used to consent each subject.**

All investigators at the University of Connecticut are responsible for complying with the attached IRB "Responsibilities of Research Investigators."

Re-approval: It is the investigator's responsibility to apply for re-approval of ongoing research at **least once yearly**, or more often if specified by the IRB. The Re-approval/Completion Form (IRB-2) and other applicable re-approval materials must be submitted **six weeks** in advance of the expiration date noted above.

Modifications: If you wish to change any aspect of this study, such as the procedures, the consent forms, the investigators, or funding source, please submit the changes in writing to the IRB using the Amendment Review Form (IRB-3). All modifications must be reviewed and approved by the IRB prior to initiation.

Audit: All protocols approved by the IRB may be audited by the Post Approval Monitor.

Office of the Vice President for Research
Research Compliance Services
438 WHITNEY ROAD EXTENSION, UNIT 1246
STORRS, CT 06269-1246
PHONE 860.486.8802
FAX 860.486.1044
compliance.uconn.edu

Please keep this letter with your copy of the approved protocol.

Attachments:

1. Validated IRB-1 Application and Study Protocol
2. Validated Appendix A Form
3. Validated Participant Consent Forms
4. Validated Initial Contact Script to Potential Participants
5. "Responsibilities of Research Investigators"

H17-105

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Internal office use only:
Full Board __ Expedited __
Protocol #

(IRB-1) Protocol Application for the Involvement of Human Participants in Research
Institutional Review Board, Research Compliance Services

SECTION I: General Information

Nature of Study: (Place an "X" in the column. Check only one.)				
		Faculty Research		Graduate Research
	X	Dissertation		Undergraduate Research
		Masters Thesis		Staff Research

Study Title: Exploring Perceptions of Personhood of a Spouse in the Early Stage of Dementia

Study Objective (2-3 sentence summary of study): The goal of this proposed study is to explore how the caregiving wives perceive their husbands in the early stage of dementia, and what influences their perceptions. A 3-phase interview process will be employed in this qualitative, interpretative phenomenological analysis (IPA) study, so that approximately 8 caregiving wives can narrate their experiences in their own words. To analyze my data, I will follow the IPA recommendations for data analysis, in order to identify the common themes in the participants' experiences.

PI, Student Investigator, Correspondent Information:

	Principal Investigator (PI)	**Student Investigator** (only for Student Initiated Research)	**Correspondent** (primary point of contact for correspondence, if applicable)
Name (First, Last, Degree):	Laura K. M. Donorfio, Ph.D.	Marina Vracevic, M.A.	
Department:	HDFS	HDFS	
Mailing Address:	368 Mansfield Road, Unit 2058, Storrs, CT 06269	368 Mansfield Road, Unit 2058, Storrs, CT 06269	
Preferred Phone #:	(203) 236-9837	(860) 494-5938	
Emergency Phone # (Required Full Board, More than Min. Risk only):	(203) 236-9837	(860) 494-5938	
Preferred E-Mail Address:	laura.donorfio@uconn.edu	marina.vracevic@uconn.edu	

Very Important: Complete and attach the Appendix A form to list all UConn key personnel engaged in research and other non-UConn investigators.

Section II: Collaborating Institutions/Facilities and Other IRB Reviews (N/A)

UCONN IRB
Approved On 8/15/17
Approved Until 8/15/18
Approved By PIE/JM

Will the research be conducted only at Storrs and/or the five regional campuses, School of Law, or School of Social Work with no involvement of a collaborating institution? ___ **Yes** __ **No (If yes, skip to Section III)**

Collaborating Institutions with a Collaborative Agreement with UConn-Storrs

UConn has formal agreements with the University of Connecticut Health Center (UCHC), Hartford Hospital (HH) and the Connecticut Children's Medical Center (CCMC) that authorize one IRB to take the lead with some research protocols. This decision is made by the IRBs involved, but the PI may request which IRB he/she prefers to be the IRB of record. See the IRB website for additional information. If you are collaborating with one of the institutions listed below, place an X in the appropriate cell to indicate which institution, based on the preponderance of expected enrollment, you are requesting serve as the IRB of record or that independent IRB approval will be sought from each applicable site. If you request that UConn-Storrs be the IRB of record, place an X in the appropriate cell.

Institution Name	% to be enrolled/consented	Requested IRB of Record	Independent IRB Review
UConn Health Center			
Hartford Hospital			
Connecticut Children's Medical Center			
UConn – Storrs			

Provide additional comments as needed:

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain: _____

Other Collaborating Institutions/Facilities

If you are collaborating with other sites, provide the name of each institution/facility (e.g. other university, K-12 school, nursing home, tribal affiliation, etc.) and describe the type of involvement of each institution (e.g. recruitment, enrollment/consenting, study procedures, follow-up, data analysis). Indicate if IRB approval/site permission is attached (indicate yes, no, or pending). You will need to obtain IRB approval from every collaborating institution that has an IRB before you can initiate research there.
Note: tabbing out of the bottom right cell will insert another row if needed.

Name of Institution	Describe Involvement	IRB Approval/Site Permission Attached?

Provide additional comments as needed:

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain: _____

International Research

Will any aspect of the study take place outside of the United States? ___ **Yes** _X_ **No**
(If yes, complete table below)

NOTE: You may need to obtain IRB approval in the country where the research is taking place and/or a Federal-wide Assurance with the Office of Human Research Protections (OHRP). Please see the IRB website for additional information.

List Location(s)	Name of Collaborating Institution/Facility	Describe Involvement	IRB/Ethics Approval and/or Site Permission Attached?

Provide additional comments as needed:

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain: _____

SECTION III: Funding (N/A)

It is the responsibility of the Principal Investigator to notify the IRB via an Amendment (IRB-3) or at Re-Approval, on an IRB-2 form if the funding source changes in any way.

Funding Source: (Place an "X" in the column next to the funding source.)		Departmental Funds		Human Rights Institute
		External (including subawards)		Research Incentive Account
		Faculty Grants (Large/Small)		Faculty Start-Up Funds
		Graduate School DDF or EE Award		Investigator Out-of-Pocket
		Office of Undergraduate Research Award	X	Unfunded

For Internal, UConn Funded Studies:

If the research is supported either in whole or in part by internal funds (Internal Program Support, Office of Undergraduate Research, Research Incentive Accounts, etc) one COMPLETE copy of each grant application (if applicable) must be included with this application.

Name of Internal/UConn Funding Source:	
Principal Investigator:	
Grant Title (if applicable and if different from protocol title):	
KFS Account Number (if known and only applicable for Faculty Large and Small Grants funded by Internal Program Support)	
Proposal Number (if applicable, e.g. PD00-0000):	
Grant Status (i.e., pending/awarded):	

Provide any additional comments as needed:

Note: If there is more than one funding source, copy the table format and add the additional funding source.

For Externally Funded Studies:

If the research is supported either in whole or in part by external funds (federal, state or private), one COMPLETE copy of each grant application or contract must be included with this application.

For each funding source, please identify the following:

NOTE: If the PI on the grant/contract is not the PI on this IRB protocol, submit an e-mail with this application in which the PI who is receiving the grant acknowledges use of this protocol under the grant.

Name of Funding Source I (if UConn is the recipient of a subaward, list the institution providing the funding then list the primary source of funds):	
Principal Investigator of Contract/Grant:	
Contract/Grant Title: (if different from protocol title)	
KFS Account Number:	
OSP Proposal Number:	
Grant/Contract Status: (i.e., pending/awarded)	

Will funds from this contract/grant be awarded to an individual or institution (via a PSA or subcontract) that will be engaged in human participant research? ___ **Yes** ___ **No**
If yes, indicate the name of the institution: _____
Provide any additional comments as needed:

Name of Funding Source II(if UConn is the recipient of a subaward, list the institution providing the funding then list the primary source of funds):	
Principal Investigator of Contract/Grant:	
Contract/Grant Title: (if different from protocol title)	
KFS Account Number:	
OSP Proposal Number:	
Grant/Contract Status: (i.e., pending/awarded)	

Will funds from this contract/grant be awarded to an individual or institution (via a PSA or subcontract) that will be engaged in human participant research? ___ **Yes** ___ **No**
If yes, indicate the name of the institution: _____
Provide any additional comments as needed:

Note: If there are more than two funding sources, copy the table format and add the additional funding source.

SECTION IV: Conflict of Interest (only required for externally funded research) (N/A)

At the time of proposal submission to the Office for Sponsored Programs (OSP), all investigators and key personnel are required to submit a Significant Financial Interest Review Form to OSP. For more information, please go to the Conflict of Interest Committee website, http://www.compliance.uconn.edu/conflict.cfm.

Is any investigator listed on this protocol required to submit the follow-up form, *"supplemental"* Significant Financial Interest Review Form? ___ Yes ___ No

If yes, please identify each individual: _____

SECTION V: Human Participants

Place your responses BELOW, not within, the box containing each item's description.

How many participants will be enrolled?
If you are enrolling more than one population describe the total enrollment for each. Note: Participants are generally considered to be 'enrolled' when they sign the consent form or have gone through an oral consent process. Therefore, be sure to account for attrition in your enrollment number.

I will enroll ten (10) participants.

If applicable, how many potential participants will be screened?
When screening procedures are conducted as part of the consent process, participants that fail to screen will be counted as being enrolled in the study.

I will screen until I have ten (10) participants eligible for the study.

Participant Population(s):
Describe the participant population(s) including gender, ethnicity, age range, income, level of education, and language spoken.

Gender: Females
Ethnicity: All ethnic groups
Age: All
Income: All
Level of education: All
Language spoken: English

The target population for this study is caregiving wives who are caring for a husband in the early stage of dementia at home, and whose husband is over the age of 70 years.

Recruitment:
Describe the recruitment process including *who* will recruit, *when* and *where* recruitment will take place and *how* participants will be identified and recruited (e.g., direct recruitment by study team in person, on the phone, by mail/email/internet, random sampling, referrals from other participants, snowball sampling and/or healthcare providers). Attach copies of all advertisement/recruitment materials for IRB review including phone scripts, web postings, newspaper advertisements. If recruiting at off-campus sites, written permission and/or local IRB approval may be required.

I will employ the purposive sampling procedures to select the potential participants for this study (Smith & Osborn, 2008). I will visit the support groups for caregiving spouses of the Alzheimer's Association in Southington CT, and I will give a short description of this study's purpose. Next, I will ask the support group participants if they would like to participate in my study. The leadership of the Alzheimer's Association, has allowed me to pursue potential participants in their support groups upon the approval of the current study.

The purpose of my initial contact with the potential participants will be to introduce myself, to explain the purpose of my study, and to ensure that the participants meet the basic eligibility requirements of the study. In Appendix B, I have included an initial contact recruiting script, and the basic eligibility questions. If the participants meet this basic criteria for the study, I will review the Informed Consent form with them, and answer any questions. I will provide the participants the

consent form, asking them to sign and return the form to me when they are ready to begin participating in the study. I will arrange to collect the form in person if the participants choose to keep the form for review beyond this initial meeting.

Following this initial meeting of the participants, I will arrange for the most convenient time to administer the final eligibility screening instrument, the Functional Assessment Staging Test (FAST) (Reisberg, 1988; Reisberg, 2007) to those who have enrolled in the study. This interview-based assessment instrument is used to evaluate functional abilities of a person with dementia, and is founded on the observations of the person's family or professional caregiver. The seven functional stages of the scale range from "normal older adult" (Stage 1) to "severe dementia" (Stage 7). The early stage of dementia, represented by Stage 3 and 4 on the FAST scale, is characterized by increasing memory loss which becomes apparent to family, close friends and co-workers. The effected individual becomes less able to remember names of persons just introduced to them. He or she may have difficulty with finances, counting money, and travel to new locations. Finally, the person's knowledge of current and recent events decreases. I have included this assessment instrument with a description of symptoms of each of the seven stages in Appendix C.

Special Population(s):
Identify any special participant population(s) that you will be **specifically targeting** for the study.

Check **all** that apply: (Place an "X" in the column next to the name of the special population.)		Minors		Economically/Educationally Disadvantaged
		Prisoners		Members of the Armed Forces
		Pregnant Women/Neonates		Non-English Speaking
		Decisionally Impaired		Individuals Living with AIDS/HIV
		UConn Students		Other (Please identify):
		UConn Employees		

UConn Students or Employees:
Are you recruiting students who are in a class you teach or for which you have responsibility? ___ **Yes** ___ **No**
Are you recruiting employees who report to you? ___ **Yes** ___ **No**

If 'Yes," explain why this population is necessary to the study and indicate precautions taken by the researchers to minimize potential undue influence or coercion:

_____

_____

SECTION VI: Drugs/Devices, Genetic Testing, Radiation and Biological Samples (N/A)

Drug/Device Use
Does the study involve the use of any of the following (check all that apply)?

- An FDA approved drug or medical device ___ **Yes** __x_ **No**
- An investigative/unapproved drug, supplement or medical device ___ **Yes** _x__ **No**
- A non-medical device ___ **Yes** _x__ **No**
- A proprietary product ___ **Yes** _x__ **No**
- A biological agent ___ **Yes** _x__ **No**

If yes, please complete the **Drug/Device Supplemental Form** (IRB-1A) and attach it to this application.

Biological Samples
Does the study involve the use of biological samples?
(Either banked or prospectively obtained) ___ **Yes** __x_ **No**
If 'Yes,' you will need to obtain approval from the Biosafety Officer before the study can be initiated. Please attach a copy of the approval letter if approval has already been granted from the BSO.

Genetic Testing
Does the study involve the genetic testing of biological samples? ___ **Yes** _x__ **No**
If yes, please complete the **Genetic Testing Supplemental Form** (IRB-1B) and attach it to this application.

Radiation or Radioisotopes
Does the study involve the use of radiation or radioisotopes? ___ **Yes** _x__ **No**
If yes, you will need to obtain approval from the Radiation Safety Officer before the study can be initiated. Please attach of copy of approval letter if approval has already been granted from the RSO.

SECTION VII: Research Plan

(The list of works cited in this proposed study and the study's appendices can be found at the end of this application).

Purpose
State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s).

In a society that strongly values people based on their independence, functionality and rationality, when a progressive cognitive decline like dementia results in a loss of memory, communication difficulties, and inability to function independently, the personhood of the afflicted individual is questioned on a basic level (Buron, 2008; Kitwood, 1997; Palmer, 2013; Swinton, 2007). Thomas Kitwood (1997), a proponent of a person-centered approach in the field of dementia care, defined personhood as "a standing or status that is bestowed upon one human being, by others, in the context of relationship and social being. It implies recognition, respect and trust" (p. 8). Starting in the late 1980's, Kitwood spent time working in long-term dementia care settings in the United Kingdom, where he witnessed a lack of regard for personhood, preferences, and routines of the residents with dementia (Kitwood, 1997). He came to realize that diminishing quality of life of people with dementia results not only from the symptoms of this disease, but also from the way that they are treated by their formal caregivers. He named this phenomenon of diminishing personhood through poor care practices a malignant social psychology. Kitwood's assessment of the state of dementia care at the time, and his consequent efforts towards improving it, stimulated the interest in a lived experience of people with dementia in the United Kingdom and United States.

To this day, however, a dominant model in the treatment and care of people with dementia is the biomedical model that focuses on symptoms and pathology of the body and mind (Buron, 2009; Doyle & Rubinstein, 2014; Wellin & Jaffe, 2004). Consequently, and regardless of Kitwood's sharp criticism of this model of care and the ensuing evidence about positive outcomes of the person-centered care with demented residents in the long-term care settings, a regard for personhood in dementia care practice continues to be understated and not fully understood (Burack, Weiner & Reinhardt, 2012; Chenoweth, King, Jeon, Brodaty, Stein-Parbury, Norman, Hass & Luscombe, 2009; Sloane, Hoeffer, Mitchell, McKenzie, Barrick, Rader, Stewart, Talerico, Rasin, Zink & Koch, 2004).

In terms of family caregiving research, the last two decades have seen a small volume of predominantly qualitative studies that explored how families preserve personhood of their loved ones with dementia (Kaldjian, Shinkunas, Bern-Klug & Schultz, 2010; O'Sullivan, Hocking & Spence, 2014; Phinney, 2006; Purves, 2011, Svanstrom & Dahlberg, 2004). Of these family caregiving studies, a few focus on a lived experience of couples with dementia and finds that marriage partners make adjustments in their roles and long-held daily routines in order to sustain personhood of the spouse with dementia, and an identity as a couple (Hellström, Nolan & Lundh, 2007; Hellstrom, Nolan & Lundh, 2005; Molyneaux, Butchard, Simpson & Murray, 2012). These studies are valuable to the examination of personhood, because they reveal that marriage partners work together to accomplish tasks of daily living, and consequently, attest to the importance of the partner with dementia to the sustenance of the couple's relationship and identity.

The work of Calasanti and Bowen (2006) and Perry and O'Connor (2002) examined the strategies that caregiving spouses employ to preserve the personhood of their partner with dementia. Calasanti and Bowen (2006) found that caregiving spouses implemented care practices that helped preserve gendered identity of their spouse. For example, they found that husbands learned new skills, such as applying makeup, fixing hair, and ironing clothes, in order to help their wives get ready in the morning. In the second study, Perry and O'Connor (2002) found that caregiving spouses supported existing competencies of their spouse with dementia by setting up tasks and situations where they would perform successfully, and by avoiding situations where their spouses could potentially experience failure. We learn from these studies that preserving personhood of the family members with dementia means preserving their functioning abilities and appropriate physical appearance.

Finally, a subset of studies on the topic of personhood focuses on subjective experience of people with dementia (McFadden, Ingram & Baldauf, 2001; Nowell, Thornton & Simpson, 2011; Phinney, Chaudhury & O'Connor, 2007). These studies are particularly valuable to the examination of personhood in dementia, because they challenge the popular notion that the associated cognitive decline destroys all aspects of the self that enable one to experience his or her life in a meaningful way. For example, in a community-based residential facility study, McFadden, et al., (2001) found that the elderly in moderate and advanced stages of dementia engaged with their environment and displayed a range of feelings, sensitivity and caring, and used humor in their interactions with others. These findings demonstrate that even late in the disease process, people with dementia lead lives with meaning.

Although the biomedical perspective dominates the treatment and care of people with dementia, as the family caregiving research indicates, spouses invest great effort in preserving personhood of their loved ones. However, no studies to date have explored caregivers' perceptions of the personhood of their afflicted spouses. Of particular interest to this proposed study are caregiving spouses' perceptions about their partners' personhood in the early stage of dementia (ESD). Research suggests that couples often lack pertinent information and continued support following a diagnosis of dementia, which can lead to difficulty in adjusting to a dementia-related decline, changes in the lifestyle, marriage, and long-held roles within the relationship (Pesonen, Remes & Isola, 2013; Robinson, Clare & Evans, 2005; Stokes, Combes and Stokes, 2012). The goal of this proposed study is to explore how a caregiving spouse perceives his/her partner with dementia early in the dementia journey, and what influences these perceptions.

Research Questions:

1. What meaning do caregiving spouses give to the cognitive, behavioral, social, and physical changes in their partners in the early stage of dementia?

2. What are caregiving spouses' perceptions of personhood of their spouse in the early stage of dementia?

3. What influences caregiving spouses perception of the personhood of their partner in the early stage of dementia?

Introduction
Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.

Today, more than 6.7 million Americans suffer from dementia, a condition associated with progressive decline in memory, attention, critical thinking, visual perception, body movement, communication, and language abilities severe enough to interfere with normal daily functioning. A leading cause of dementia is Alzheimer's disease. It accounts for 60%- 80% of all dementia. It is estimated that the incidence of dementia will more than triple by the year 2050 in association with the increase in the aging population in the United States ("2014 Alzheimer's Disease Facts and Figures," 2014).

In an attempt to address this imminent health crisis, many multidisciplinary research efforts are under way to find ways to prevent and cure dementia, and to develop proficient care and support for affected individuals and their caregivers ("2014 Alzheimer's Disease Facts and Figures," 2014). Although significant progress has been made (e.g., it is now possible to diagnose dementia early before it significantly impacts one's functioning abilities, a medication that helps slow down a progression of dementia is available for use in treatment, etc.), at this time, there is no cure, a way to prevent, or to stop the progression of dementia. Consequently, many individuals and families continue to struggle with this disease.

According to the Alzheimer's Association report, in 2013, 15.5 million caregivers provided more than 17.7 billion hours of unpaid care valued at $220.2 billion ("2014 Alzheimer's Disease Facts and Figures," 2014). By the year 2050, the incidence of dementia is projected to increase threefold, and the value of care provided by families and friends will reach $1.2 trillion ("2014 Alzheimer's Disease Facts and Figures," 2014).

About one quarter of all individuals living with dementia are cared for by their spouses (Fisher, Franks, Plassman, Brown, Potter, Llewellyn, Rogers & Langa, 2011). Persons with dementia require increasing assistance with activities of daily living (ADL), management of neurodegenerative symptoms (e. g., forgetfulness, lack of sufficient judgment about people and situations, difficulties with understanding and using language, etc.), and management of challenging behaviors (e. g., agitation, anxiety, inappropriate social conduct, etc.) caused by progressive deterioration in their cognitive functioning ("2013 Alzheimer's Disease Facts and Figures," 2013). In addition to providing assistance with daily functioning to their partners with dementia, the caregiving spouses play a very significant role in helping them make emotional adjustments as the disease unfolds (Robinson, Gemski, Abley, Bond, Keady, Campbell & Manthorpe, 2011; Sorensen, Waldorff & Waldemar, 2008). As the afflicted spouse experiences many losses in the course of dementia, including personality changes and forgetfulness, their caregiving spouse, a vital social relation, and in many cases, a life-long partner works very hard at preserving their identity and the marriage relationship (Calasanti & Bowen, 2006; Davies, 2011; Gilies, 2012; Hellstrom, Nolan & Lundh, 2005).

Design, Procedures, Materials and Methods
Describe the study design, including the sequence and timing of all study procedures. Indicate expected start and completion dates. Include screening procedures, if any. The IRB strongly suggests that investigators incorporate flexibility

into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained. If the study involves use of deception explain the reason why this is necessary. If applicable, describe the use of audiotape and/or videotape and provide justification for use. If this study offers **treatment** for the participants' condition, complete the **Treatment Study Supplemental Form** (IRB-1C) and attach it to this application for review. **If the study includes measures, survey instruments and questionnaires, i**dentify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study.

Study Design and Setting

In this qualitative study, I will employ an interpretive phenomenological analysis (IPA) in order to explore the caregiving spouses' perceptions about the personhood of their partner with dementia, and the meaning they assign to the dementia-related cognitive, behavioral, social, and physical changes in the spouse. Interpretive phenomenological analysis aims to explore an individual's personal perception of a situation or an event, as opposed to attempting to produce an objective understanding of the phenomenon (Smith & Osborn, 2008). Its goal is to take a perspective of the participant in respect with understanding the lived experience of a phenomenon of interest, and to understand how a participant is making sense of his personal and social world. While a goal of IPA is to gain a close understanding of the the respondent's personal world, it is acknowledged that this cannot be completely accomplished. Instead, the access is dependent on the researcher's own conceptions which are required to make sense of the respondent's personal world through a process of interpretative activity. The setting for this study will not be limited to a specific place, as the primary goal is to recruit the participants who have experienced the phenomenon.

Data Collection Methods

Following the recommendations of Seidman (2005), in order to gain an understanding of a lived experience of the caregiving spouses in my study, and the meaning they give to their experience as it relates to phenomenon of personhood in dementia, I will employ a series of three in-depth interviews. The interviews will be semi-structured, and will consist of open-ended questions to allow the participants to tell their stories in their own words. The three-series interview begins with exploring a context of the participant's experience as it relates to the phenomenon under study (1st interview), followed by the deeper exploration of the participant's present experience of the phenomenon (2nd interview), and ends with inviting the participant to reflect more deeply on the meaning of the experience (3rd interview). Although the focus of this study is on the meaning that caregiving spouses give to their spouse's symptoms of decline, and consequent perceptions of the spouse's personhood, Seidman argued that the three interview series allows the investigator and the correspondent to adequately set the participants' experience under study in the broader context of their life. Seidman (2005) wrote: "People's behavior becomes meaningful and understandable when placed in the context of their lives and the lives of those around them. Without context, there is little possibility of exploring the meaning of an experience" (p. 16-17). For a purpose of attaining a more complete understanding of a context of the participant's experience as it relates to the phenomenon under study, the first interview protocol encompasses a set of questions about the participant's prior knowledge of dementia. It is possible that wives in this study will have diverse caregiving experience, knowledge of the disease process, and a familiarity with individuals suffering from dementia, which may impact the wives' perceptions of personhood of their afflicted husbands. For each participant, each of the three interviews will last between 60 and 90 minutes (a total of 3 – 6 hours for each participant), and each interview will occur 3 days to one week apart (Seidman, 2005). See Appendix A for the interview protocol.

Data Collection Procedures

I will employ the purposive sampling procedures to select the potential participants for this study (Smith & Osborn, 2008). I will visit the support groups for caregiving spouses of the Alzheimer's Association in Southington CT, and I will give a short description of this study's purpose. Next, I will ask the support group participants if they would like to participate in my study. The leadership of the Alzheimer's Association, has allowed me to pursue potential participants in their support groups upon the approval of the current study.

The purpose of my initial contact with the potential participants will be to introduce myself, to explain the purpose of my study, and to ensure that the participants meet the basic eligibility requirements of the study. In Appendix B, I have included an initial contact recruiting script, and the basic eligibility questions. If the participants meet this basic criteria for the study, I will review the Informed Consent form with them, and answer any questions. I will provide the participants the consent form, asking them to sign and return the form to me when they are ready to begin participating in the study. I will arrange to collect the form in person if the participants choose to keep the form for review beyond this first meeting.

Following this initial meeting of the participants, and after the consent forms have been reviewed, signed and returned to me, I will arrange for the most convenient time to administer the final eligibility screening instrument, the Functional Assessment Staging Test (FAST) (Reisberg, 1988; Reisberg, 2007) to those enrolled in the study. This interview-based assessment instrument is used to evaluate functional abilities of a person with dementia, and is founded on the observations of the person's family or professional caregiver. The seven functional stages of the scale range from "normal older adult" (Stage 1) to "severe dementia" (Stage 7). The early stage of dementia, represented by Stage 3 and 4 on the FAST scale, is characterized by increasing memory loss which becomes apparent to family, close friends and co-workers. The effected individual becomes less able to remember names of persons just introduced to them. He or she may have difficulty with finances, counting money, and travel to new locations. Finally, the person's knowledge of current and recent events decreases. I have included this assessment instrument with a description of symptoms of each of the seven stages in Appendix C.
Next I will arrange for the most convenient time for the first interview to take place. All interviews will be conducted via phone, and will be audio-recorded and transcribed. I anticipate that the first interview will last between 60 and 90 minutes. Upon completion of the first interview, I will arrange for the second interview to take place within 3 to 7 days following the first interview. Equally, upon completion of the second interview (60-90 minutes in duration), I will arrange for the last interview to take place within 3 to 7 days following the second interview. I anticipate that the last interview will last between 60 and 90 minutes.

After all the interviews have been transcribed, I will member check with the participants to ensure that all information is accurate. I will deliver the transcripts to the participants in person, and I will ask them to make any necessary corrections, and contact me so that I can collect the transcripts.

Finally, I will follow up with the participants 3 - 6 months after all the interviews are completed in order to find out if they are in need of any support, and to inquire if they have anything to say that relates to our earlier interviews.

Justification of Sample Size/Data Analysis

Justification of Sample Size: For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition, with references as

appropriate. Data Analysis: For all studies, provide a description of the statistical or qualitative methods used to analyze the data.

Justification of Sample Size

Smith and Osborn (2008) state that sample size in interpretive phenomenological analysis (IPA) studies depends on "the degree of commitment to the case study level of analysis and reporting, the richness of the individual cases, and the constraints one is operating under (p. 56). While they do not make specific recommendations about a sample size, Smith and Osborn suggest that a sample size of 3 to 6 participants is recommended for student researchers. No studies were identified that employed IPA in exploring personhood in dementia with a population of spouses caregivers. Two family caregiving studies that explored general caregiving experiences of spouses of persons with dementia, and that utilized IPA as a method of inquiry, had sample sizes of 7 and 6 participants respectively (O'Shaughnessy, Lee & Lintern, 2010; Walters, Oyebode & Riley, 2010).

Data Analysis

The assumption of IPA is that "meaning is central, and the aim is to try to understand the content and complexity of those meanings rather than to measure their frequency" (Smith & Osborn, 2008, p. 66). After I transcribe all the interviews and complete the member checking with the participants, following the recommendation of Smith and Osborn (2008) I will begin by reading and re-reading the transcripts to become familiar with the material. I will start my analysis with one case at the time. First, I will make initial comments "on similarities and differences, echoes, amplifications and contradictions in what a person is saying" throughout the first transcript (Smith & Osborn, 2008, p. 67). Second, I will go back to the beginning of the transcript and document the emerging themes, by transforming the initial notes into phases that capture the overall meaning of what was found in the transcript. Smith and Osborn wrote that these theme phrases should "allow theoretical connections within and across cases but…still [be] grounded in particularity of a specific thing said" (Smith & Osborn, 2008, p. 68). Third, I will look for the connections between the emerging themes, and I will cluster the ones that appear to belong together. At this point, as Smith and Osborn inform, some themes may emerge as superordinate concepts with lower-order themes clustered around them. The themes that do not fit well with the emerging structure may be discarded or kept for further analysis later when the rest of the cases are analyzed in the same way. This concludes the initial analysis of the first transcript. The next step is to analyze other transcripts. Smith and Osborn state that the themes from the first case can be used to orient the subsequent analysis, or start fresh, all the while discerning between the repeating and newly-emerging themes.

Once all the cases have been analyzed, I will construct the final table of superordinate themes. Following Smith and Osborn's recommendation, I will focus on the themes that are most prevalent in the data, as well as the ones that best represent the "richness" of the data.

Inclusion/Exclusion Criteria
List major inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.

The target population for this study is caregiving wives who are caring for a husband in the early stage of dementia at home, and whose partner is over the age of 70 years. The score of 4 (a.k.a. "Stage 4") on the FAST scale will be used as a cut off score for eligibility in the study. For the purpose of clarity of the study decision was made to focus on female spouses, because of the known differences in how man and women approach caregiving (Bédard, Kuzik, Chambers, Molloy, Dubois &

Lever, 2005). In line with IPA recommendations, because the goal is to report about a particular group, this study will employ a purposive sampling procedure (Smith & Osborn, 2008). The more advanced the people are in the disease process, the more their personhood becomes "at risk" of being diminished, and therefore, it is important to examine perceptions of personhood throughout the course of dementia (Kitwood, 1997; Sabat, Napolitano & Fath, 2004). However, the currently proposed study is concerned with wives' perceptions of personhood of their husbands in the early stage of dementia, because these couples face dramatic transitions in their daily life, including the initial emotional impact of the disease, challenges in daily functioning, and changes in roles and relationships (Pesonen et al., 2013; Robinson et al., 2005; Yale, 2013). The study's sample will also be limited to spouses who are caring for their loved ones at home, as most people who are in the early stage of dementia, according to the Alzheimer's Association, are still living at home. Also, the study's sample will be limited to spouses who are caring for a person with dementia over the age of 70 years, because they typically face different challenges in terms of the nature and progression of the disease, and lifestyle issues from people with dementia under the age of 70, generally considered as the "earlier onset" dementia sufferers (Armari, Jarmolowicz & Panegyres, 2013; Vugt, Koopmans, Bakker, Verhey & Vliet, 2010). The caregiving wives whose husbands with dementia have the following health conditions, HIV/AIDS, leprosy, diabetes, cancer, obesity, skin disorders, venereal diseases, and mental illnesses other than dementia will be excluded from this study, because the research literature shows that these are among the highest stigmatized health conditions (Engebretson, 2013; Hillson, 2014; Puhl & Heuer, 2010; Sartorius, 2007). By excluding participants with these health conditions, I am attempting to eliminate an impact that these conditions may have on how the personhood of the husbands with dementia is perceived by the caregiving wives in this study. Finally, the last criterion for inclusion in this study is that caregiving wives are able to understand, speak, read and write the English language at an advanced or native proficiency level.

Risks and Inconveniences
Describe the potential risks to participants (and secondary participants, if applicable) and *steps taken to minimize risks*. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).

Risks: Psychological distress while reflecting on the meaning that having a husband with dementia has for the participant during and following the interviews. To address this potential risk, I will ask each participant at the beginning and at the end of each interview if she feels positive about speaking with me today and /or last time. If the participant says: "yes", I will proceed with the interview, if the participant says: "no," I will ask the participant if she would prefer not to continue with the interview process, or if she would like to reschedule interview for another, more convenient time. Also, if the participant states that she does not feel positive about participating in previous or future interviews during this study, I will ask her if she is need of support, and I will refer the participant to the local Alzheimer's Association Chapter for further support. Finally, I will follow up with all participants 3-6 months following the last interview, and ask if they are in a need of any support.

Inconveniences: Time invested into interview process. Each participant will be interviewed three times, for 60 – 90 minutes each time. Interviews will be scheduled 3-7 days apart or to accommodate the participant's schedule. In order to address this potential inconvenience, the participant will be informed of the time required for involvement in this study, at the beginning of the study (during the initial contact), in addition to being informed that her participation in the study is voluntary and that she can drop out of the study for any reason, at any time during the study.

Benefits
Describe anticipated benefits to the individual participants. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children). Do not include compensation or earned course credits in this section.

Anticipated benefits to individual participants: Opportunity to reflect on what it means for her (the participant) to have a husband with dementia, and to share their stories with someone who is interested in their unique experience.

Anticipated benefit to society: This study will contribute an insight regarding how some spouses view their partner early in the disease process, and an insight regarding challenges that some caregiving spouses face early in the disease process.

Anticipated benefit to broader population of wives whose husbands are in the early stages of dementia: Insight regarding an experience of others, who, like they are living with, and caring for a spouse in the early stage of dementia

Risk/Benefit Analysis
Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.

I believe that the benefits outweigh the risks in this proposed study for the following reasons. While the caregiving wives may experience psychological distress when reflecting on the meaning of having a husband who is suffering from dementia, they may also potentially benefit from the opportunity to express their emotions and opinions in a private interview environment. Furthermore, the participants may also benefit from the opportunity to know that sharing their caregiving experience will serve as a valuable insight in the field of study on dementia caregiving, and a validation to others who also have spouses with dementia.

Economic Considerations
Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.

N/A

Data Safety Monitoring
This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies determined to be exempt from continuing IRB review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring *before* completing this section - http://irb.uconn.edu/irb_sop/IRBSOP_submission.html#data_safety_monit.

Issues that should be addressed in the DSMP include the following:
1) frequency of the monitoring
2) who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.)
3) what data will be monitored
4) how the data will be evaluated for problems
5) what actions will be taken upon the occurrence of specific events or end points

6) who will communicate to the IRB and how communication will occur

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

Items: 1, 2 and 3: Interview transcripts will be stored electronically on a flash drive, and printed interview transcripts will be stored in in a locked cabinet in PI's Storrs Campus office, and will be monitored by the PI in conjunction with the student investigator once every two weeks.

Items 4, 5 and 6: The interview transcripts will be reviewed to monitor for clarity. The PI will communicate any arising problems to IRB.

Privacy/Confidentiality

Explain how the privacy interests of participants will be maintained during the study (note that privacy pertains to the individual not to the data). Describe procedures for protecting confidentiality of data collected during the study and stored after study closure. Describe how data will be coded. Describe plans for storage and security of electronic data (plan must comply with the University's Policy on the Security Requirements for Protecting University Data at Rest). If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.

From the onset of the recruitment process, all identifiable data about the participants will be encrypted. Each participant will receive a unique code which consists of a random number (e.g., between 1 and 1000). A link between each participant's unique code and her identifiable information will be kept in a separate, locked in PI's office at the Storrs UConn Campus.

At the time of the review of the Informed Consent, the participants will be briefed about the interview process, and will be advised to schedule the interviews in an isolated setting in order to ensure the privacy of the information shared with the interviewer (the student researcher), during the interview.

During the data collection phase, the interviews will take place over the phone between the student researcher and each individual participant. The student researcher will also make sure that she is located in an isolated setting in order to ensure the privacy during the interviews. The interviews will be audio-recorded, and the audio files will be stored on a separate, password-protected flash drive. Once that each individual interview is completed, it will be transcribed on the computer, and stored electronically, on a password-protected flash drive separate from its corresponding audio file. The two will be linked with a unique code created at the screening phase of the study, linking to the participant's identifiable information.

At the analysis phase of the study, the transcripts of the participants' interviews will have to be printed on a paper to allow for a thorough analysis process. The student researcher will transcribe these files. These printed files will be stored in in a locked cabinet in PI's Storrs Campus office.

Following the completion of the study, once all the dissertation requirements are satisfied and upon being instructed by the PI, the student researcher will physically destroy all the keys, flash-drives, delete all electronic files of the data, and will shred all the printed, paper files of the data (3 years following a completion / termination of the study. per federal

regulations (45 CFR 46.115(b) and 21 CFR 56.115(b))). No de-identified data will be retained indefinitely.

The only time when the confidentiality cannot and will not be maintained is if a study participant yields information that leads the student researchers and the PI believe that there may be abuse / neglect/ exploitation occurring. In this case the PI will make a report of a suspected neglect / abuse / exploitation to Protective Services for the Elderly, State of Connecticut Department of Social Services.

SECTION VIII: Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent Setting
Describe the consent process including *who* will obtain consent, *where* and *when* will it be obtained, and *how* much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).

During my initial contact with the potential participants, I will review the Informed Consent form with her, and answer any questions. Upon receiving her verbal consent, I will give the participant the consent form, and ask her to sign and return the form to me at her convenience. If the participant chooses to keep the consent form beyond the initial meeting, I will arrange to collect the form in person, at the participant's convenience. The Informed Consent forms of each individual participant will receive a unique code and will be stored in a locked cabinet in PI's Storrs Campus office.

Capacity to Consent
Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).

For purpose of this study, we will be recruiting adult caregiving wives of husbands in the early stage of dementia, so we do not anticipate having participants with limited decision-making capacity, nor do we anticipate having study participants with language berries, as one of our basic study participation requirements is that the participants understand, speak, read and write the English language at advanced or native proficiency level.

Caring for someone with dementia can be a strenuous task, so having an individual with a limited decision-making capacity in a caregiving role may result in a dangerous situation (e.g., inadequate care, neglect, etc.) for both the caregiver and a care receiver. If in the course of our recruitment process we come across participants who disclose or demonstrate signs of a possibly dangerous or inadequate caregiving situation, we will make a report to the Protective Services for the Elderly and express our concerns for well-being of the couple.

Parent/Guardian Permission and Assent

If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.

N/A

Documentation of Consent
Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).

The Adult Consent Form (basic) will be used in this study. It is attached to this application.

Waiver or Alteration of Consent
The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of signed consent** (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:

N/A

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception in research):

- Why is the study considered to be minimal risk?

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.

- Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.

- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.

Waiver of signed consent (i.e. participants give consent only after reading an information sheet):

- Why is the study considered to be minimal risk?

- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.

- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

HIPAA Authorization
On the Storrs campus, the following sites are covered entities under the Health Insurance Portability and Accountability Act:

1. Nayden Rehabilitation Clinic (outpatient physical therapy)
2. Speech and Hearing Clinic
3. Emergency Medical Services (EMS, Ambulance)

If research participants are recruited through these entities, it may be necessary to obtain a Waiver of Authorization to allow you to access records for recruitment and an Authorization to use and disclose Protected Health Information (PHI). Contact the Office of Research Compliance at 860-486-8802 for additional information. **Note:** Student Health Services is not covered by HIPAA; however, FERPA regulations apply.

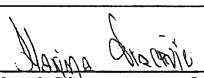
Principal Investigator Certification

I understand the University of Connecticut's policies concerning research involving human participants and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by the University of Connecticut, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;
3. To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form;
4. To report to the IRB in accordance with IRB policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval/Completion Form as needed;
6. That my participation and the participation of any co-investigators does/do not violate the University of Connecticut policy on Individual Conflicts of Interest in Research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

	5/21/2017
Original Signature of Principal Investigator	**Date**

	5/21/2017
Original Signature of Student Investigator (Only for Student-Initiated Research)	**Date**

Original Signature of Medical Monitor (Required for all studies that will be monitored by a Physician)	**Date**

Department Head Certification

This is to certify that I have read the protocol and believe that there is value in asking and answering these research questions using the approach described in this application. To the best of my knowledge, the researcher(s) have the time, facilities, and expertise to conduct this study.

Original Signature of Department Head (Required for ALL studies, unless grant application/contract is attached; see Section III)	**Date**

The Proposed Study's Literature Review References

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H.17-105

University of Connecticut
Institutional Review Board
Office of Research Compliance

Appendix A: Key Personnel and Study Investigators Log/Personnel Amendment Form

Instructions: The IRB must review and approve all changes to the Key Personnel, *before* implementation in the field. Submit this log at the time of initial review and at continuing review if changes are being made. Include the complete list of UConn Key Personnel and non-UConn Investigators. In addition, submit this form and an IRB-3 Amendment Request Form, to add or remove individuals to the protocol throughout the approval period.

Date:	Protocol # (if known):	PI Name:	Protocol Title:
7/1/2015		Laura Donorfio, Ph.D.	"Exploring Perceptions of Personhood of a Spouse in the Early Stage of Dementia"

UConn Key Personnel Engaged in Research (i.e. enroll participants, conduct consent process, collect or review data/identifiable information from participants, intervene/interact by performing invasive procedures, have access to information that links participants' names or other identifiers with their data, or act as authoritative representatives for the investigators) – Provide the following information for each person:

Name (First, Last, Degree)	**Department/ Unit #**	**Role/Primary Function Performed in Study** (see ***Important*** Note Below)	**Graduate/Undergraduate Student?** (Indicate Yes/No)
Laura Donorfio, Ph.D.	2058	Principal Investigator: Will provide supervision, guidance, and oversight for entire duration of study; Will discuss basic principles of ethical research design with the student researcher, and will in collaboration with the student develop appropriate strategies for: Recruitment/retention, consent process, data and safety monitoring plan, and writing scholarly papers and reports (UConn IRB recommendations for PI Mentoring of Undgd./Grad. Students conducting research with human subjects).	No
Marina Vracevic, M.A.	2058	Graduate student researcher conducing a dissertation research study: Recruit and enroll participants, conduct consent process, collect data (via interviews), analyze data, have access to information that links participants' names/ identifiers with their data, and write up a report of the study.	Yes

Please make sure that CITI Certification for all personnel is up-to-date. Note: tabbing out of the bottom right cell will insert another row if needed.

Other Non-UConn Investigators/Key Personnel: None

Name (First, Last, Degree)	**Affiliated Institution**	**Describe CITI (or equivalent) human subjects training**	**Role/Primary Function Performed in Study** (see ***Important*** Note Below)	**Graduate/Undergraduate Student?** (Indicate Yes/No)

Note: tabbing out of the bottom right cell will insert another row if needed.

Important: Please be specific. For example, the term "Co-Investigator" is not sufficient. You must describe the specific role (e.g. "Co-Investigator – train confederates"). For student directed research, the role of the PI may be described as "PI – oversee/mentor student researcher." For full board and expedited studies, include the specific procedures (e.g. blood draws, interview, survey distribution, acting as a confederate) each person will perform and his/her experience/training with this procedure.

Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Laura K. M. Donorfio, Ph.D.
Student Researcher: Marina Vracevic, M.A.
Study Title: Exploring Perceptions of Personhood of a Spouse in the Early Stage of Dementia

Introduction

You are invited to participate in a research study that aims to explore how caregiving wives perceive their husbands in the early stage of dementia, and what meaning they give to dementia-related psychological and physical changes in their partners.

It is estimated that by the year 2050, one in three Americans 65 years and older will be living with some form of dementia, a group of symptoms that includes over 50 known types of diseases and conditions that currently affect over 6.7 million people in the United States. Because psychological and physical decline associated with dementia impairs memory, judgment, communication and other abilities that make independent daily functioning possible, it is important to care for the afflicted individuals in a way that not only takes care of their basic needs, but also preserves their sense of self, or their personhood. Many individuals in the Early Stage of Dementia (ESD) live at home and many are cared for by their spouses. Knowing how caregiving spouses perceive their partner in the early stage of dementia can provide insight in how to better support couples living with dementia.

What are the study procedures? What will I be asked to do?

If you agree to participate in this study, I would ask that we speak over the phone on three separate occasions, so I may interview you about your perceptions of your spouse who is living with dementia. Each interview will last between 60 and 90 minutes, and with your permission, I will audiotape each of our conversations. The interviews will be scheduled 3-7 days apart, so your involvement in this study will take up to three weeks. We will schedule each interview at times most convenient for you. Your identity and the information that I collect from you will be treated confidentially.

What are the risks or inconveniences of the study?

As a participant in this study, you may experience a psychological distress while reflecting on what it means to you to have a husband with dementia. If you do experience such distress, you can asked that we stop and if necessary, discontinue the interviews indefinitely. A potential

inconvenience of participating in this study is a time invested in participating the interviews. You will be interviewed three times, for 60 – 90 minutes each time. Interviews will be scheduled 3-7 days apart or to accommodate each participant's schedule.

What are the benefits of the study?

Anticipated benefits to individual participants: Opportunity to reflect on what it means for her (the participant) to have a husband with dementia, and to share their stories with someone who is interested in their unique experience.

Anticipated benefit to society: This study will contribute an insight regarding how some spouses view their partner early in the disease process, and an insight regarding challenges that some caregiving spouses face early in the disease process.

Anticipated benefit to broader population of wives whose husbands are in the early stages of dementia: Insight regarding an experience of others, who, like they are living with, and caring for a spouse in the early stage of dementia

Will I receive payment for participation? Are there costs to participate?

There is no payment or cost for participating in this study.

How will my personal information be protected?

From the onset of the recruitment process, you will be assigned a unique code, in order to protect your personal information from being relieved to unintended sources, and to conceal a connection between your personal information and what your reveal in your interviews. Your personal information and your interviews will be stored in separate, locked places known only to the primary investigator of this study and the student researcher.

At the time of your over-the-phone interviews, you and the interviewer should both sit an isolated setting in order to ensure the privacy of the information shared.

Three years following the completion of this study, once all the dissertation requirements are satisfied all data related to this study will be permanently destroyed per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b))).

The only time when the confidentiality cannot and will not be maintained is if you reveal information that leads the student researchers and the PI believe that there may be abuse / neglect/ exploitation occurring. In this case the PI will make a report of a suspected neglect / abuse / exploitation to Protective Services for the Elderly, State of Connecticut Department of Social Services.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

What happens if I am injured or sick because I took part in the study?

In the event you become sick during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed.

If, however, you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. You also do not have to answer any questions posed by the researchers that you do not want to answer. There are no penalties or consequences of any kind if you decide that you do not want to participate, or answer a particular question. All you have to do is tell us, at any point during the study, that you do not wish to participate or answer a specific question.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, (Laura Donorfio, phone #: 203-236-9837) or the student researcher (Marina Vracevic, phone #: 860-494-5938). If you have any questions concerning your rights as a research subject, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent:

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Participant Signature:	Print Name:	Date:
Signature of Person Obtaining Consent	Print Name:	Date:

UCONN IRB
Approved On 8/15/17
Approved Until 8/15/18
Approved By PIE/JM

Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Laura K. M. Donorfio, Ph.D.
Student Researcher: Marina Vracevic, M.A.
Study Title: Exploring Perceptions of Personhood of a Spouse in the Early Stage of Dementia

Introduction

You are invited to participate in a research study that aims to explore how caregiving wives perceive their husbands in the early stage of dementia, and what meaning they give to dementia-related psychological and physical changes in their partners.

It is estimated that by the year 2050, one in three Americans 65 years and older will be living with some form of dementia, a group of symptoms that includes over 50 known types of diseases and conditions that currently affect over 6.7 million people in the United States. Because psychological and physical decline associated with dementia impairs memory, judgment, communication and other abilities that make independent daily functioning possible, it is important to care for the afflicted individuals in a way that not only takes care of their basic needs, but also preserves their sense of self, or their personhood. Many individuals in the Early Stage of Dementia (ESD) live at home and many are cared for by their spouses. Knowing how caregiving spouses perceive their partner in the early stage of dementia can provide insight in how to better support couples living with dementia.

What are the study procedures? What will I be asked to do?

If you agree to participate in this study, I will first ask you some questions about your husband's ability to perform common tasks of daily life (e.g., paying bills, driving, house work, self-care, etc.), to get a better understanding of his functioning abilities. I would then ask that we speak over the phone on three separate occasions, so I may interview you about your perceptions of your spouse who is living with dementia. Each interview will last between 60 and 90 minutes, and with your permission, I will audiotape each of our conversations. The interviews will be scheduled 3-7 days apart, so your involvement in this study will take up to three weeks. We will schedule each interview at times most convenient for you. Your identity and the information that I collect from you will be treated confidentially.

What are the risks or inconveniences of the study?

As a participant in this study, you may experience a psychological distress while reflecting on what it means to you to have a husband with dementia. If you do experience such distress, you can ask that we stop and if necessary, discontinue the interviews indefinitely. In the event of distress, you will be referred to the Alzheimer's Association for support. A potential inconvenience of participating in this study is a time invested in participating the interviews. You will be interviewed three times, for 60 – 90 minutes each time. Interviews will be scheduled 3-7 days apart or to accommodate each participant's schedule.

What are the benefits of the study?

Anticipated benefits to individual participants: Opportunity to reflect on what it means for her (the participant) to have a husband with dementia, and to share their stories with someone who is interested in their unique experience.

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Anticipated benefit to broader population of wives whose husbands are in the early stages of dementia: Insight regarding an experience of others, who, like they are living with, and caring for a spouse in the early stage of dementia

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There is no payment or cost for participating in this study.

How will my personal information be protected?

From the onset of the recruitment process, you will be assigned a unique code, in order to protect your personal information from being relieved to unintended sources, and to conceal a connection between your personal information and what your reveal in your interviews. Your personal information and your interviews will be stored in separate, locked places known only to the primary investigator of this study and the student researcher.

At the time of your over-the-phone interviews, you and the interviewer should both sit an isolated setting in order to ensure the privacy of the information shared.

Three years following the completion of this study, once all the dissertation requirements are satisfied all data related to this study will be permanently destroyed per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b))).

The only time when the confidentiality cannot and will not be maintained is if you reveal information that leads the student researchers and the PI believe that there may be abuse / neglect/ exploitation occurring. In this case the PI will make a report of a suspected neglect / abuse / exploitation to Protective Services for the Elderly, State of Connecticut Department of Social Services.

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Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. You also do not have to answer any questions posed by the researchers that you do not want to answer. There are no penalties or consequences of any kind if you decide that you do not want to participate, or answer a particular question. All you have to do is tell us, at any point during the study, that you do not wish to participate or answer a specific question.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, (Laura Donorfio, phone #: 203-236-9837) or the student researcher (Marina Vracevic, phone #: 860-494-5938). If you have any questions concerning your rights as a research subject, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent:

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Participant Signature:	Print Name:	Date:
Signature of Person Obtaining Consent	Print Name:	Date:

UCONN IRB
Approved On 8/15/17
Approved Until 8/15/18
Approved By PEE/JM

Appendix B

Initial Contact Script to Potential Participants

Hello,

My name is Marina Vracevic, and I am a Ph.D. candidate in Human Development and Family Studies, at the University of Connecticut (UConn). My reason for being here today is to tell you about my doctoral dissertation study, and to ask that you consider participating in this study. I am exploring how caregiving wives perceive their husbands in the early stage of dementia, and what meaning they give to dementia-related psychological and physical changes in their partners. Please consider participating in this study if the following applies to you:

1. You and your husband live at home;

2. Your spouse is 70 years of age or older;

3. To your knowledge, your spouse does not have any of the following health conditions: HIV/AIDS, leprosy, diabetes, cancer, obesity, skin disorders, venereal diseases, and mental illnesses other than dementia

4. You understand, speak, read and write the English language at advanced or native proficiency level.

If you agree to participate in this study, I would ask that we speak over the phone on three separate occasions, so I may interview you about your perceptions of your spouse who is living with dementia. Each interview will last about one hour, and with your permission, I will audiotape each of our conversations. The interviews will be scheduled 3-7 days apart, so your involvement in this study will take up to three weeks. We will schedule each interview at times most convenient for you. Your identity and the information that I collect from you will be treated confidentially.

If you are interested in participating in this study or if you have questions about this study, please feel free to speak to me after this meeting, or e-mail me at marina.vracevic@uconn.edu, or call me at 860-494-5938. We will review the study's Informed Consent form together in person, and you are welcome keep the form for further review, before signing and returning it to me. Your participation in this study will begin after you have reviewed and signed the Informed Consent Form. I will arrange to collect the form from you in person, at your convenience.

Thank you for your time.

Best,

Marina Vracevic, M.A.

Dept. of Human Development and Family Studies, University of Connecticut

Appendix A

Interview Protocol

Interview 1: *Establishing the context for participant's experience of phenomenon*

In this first interview, I would like to learn about your and your spouse's life before he had dementia, and also, what you knew about dementia in general before your spouse was diagnosed with this disease.

1. Please describe how your met your spouse.
2. How would you describe your courtship?
3. How would you describe early years of your marriage?
4. Do you have children?
5. What kind of work have you and your spouse done?
6. How important is religion to you and your spouse?
7. What are some talents, special skills and/or hobbies that you and your spouse have?
8. What are some highlights of your life together?
9. What are some difficult moments in your life together?

Previous knowledge about dementia:

10. What did you know about dementia before your spouse was diagnosed? (If applicable: Where did you learn this information?)
11. What did you know about people with dementia in general before your spouse was diagnosed? (If applicable: Where did you learn this information?)
12. Did you previously know anyone that had dementia? (If applicable: What was he/she like?)

13. Did you previously know anybody that cared for someone with dementia? (If applicable: What do you know from him/her about caring for someone with dementia?)
14. What are some things that you thought people with dementia can and cannot do?
15. Did you think that people with dementia are capable of recognizing our love respect and care for them?
16. Did you think that people with dementia are capable of expressing love respect and attention towards others?

Interview 2: *Encouraging the participant towards deeper exploration of the present experience of the phenomenon*

Last time we spoke about your life with your spouse before dementia. In this interview, I would like to learn specifically about your experience from the time when you started noticing changes in your spouse, through diagnosis, until the present time. I would like to know what your thoughts and reactions were to these events, and how, in your opinion, they affected your and your spouse's daily activities, marriage and lifestyle.

1. When did you first get a sense that something was "different" about your spouse?
2. Did your spouse mention anything or complain of any difficulties that made you think that something might be wrong?
3. Did something happen that alerted you to visit a doctor? (If applicable: Please share the details of the event. Please share the details of your visit to the doctor.)
4. Please share your experience of receiving the news of your spouse's diagnosis of dementia.

5. What was your initial reaction to finding out that your spouse has dementia? What were your thoughts? How did you feel?
6. What was your spouse's reaction? What were his thoughts? How do you think he felt?
7. Did your reactions change over time? How so?
8. Did things at home change as a result of your spouse having dementia? (If applicable: How so?)
9. Did anything change in your marriage as a result of your spouse having dementia? (If applicable: How so?)
10. Did anything change in your social interactions with family and friends as a result of your spouse having dementia? (If applicable: How so?)
11. Have you shared the diagnosis with any of your family members and/or friends? Why / why not? (If applicable: What was the reaction of your friends and family to

Interview 3: *Inviting participants to reflect on the meaning that the experience holds for them*

When we spoke the last time, I asked you about the details of your experience of learning that your spouse has dementia, and how your spouse's condition impacted on your daily life, relationship and lifestyle. In this last interview, I would like to learn if your spouse has changed as a result of having dementia, and in what ways he/she has changed.

1. Do you believe that your spouse has changed as a result of having dementia? (If applicable: In what ways? If not, why?)
2. Do you think that your spouse is the same person as he/she was before dementia?

3. Does your spouse talk about feeling changed by dementia? (If applicable: If so, in what ways? If not, why do you think that he/she does not feel changed by the disease?)
4. Do you think others think of him as a different or same person? (If applicable: If so, in what ways? Why do you think others think that he is changed or stayed the same?)
5. What, or who do you rely on to deal with your spouse's condition?
6. Do you think that these resources influence how you perceive your spouse?
7. In what ways do these resources influence how you perceive your spouse?

Appendix C

Functional Assessment Staging Test (FAST)

FAST SCALE ADMINISTRATION

The FAST scale is a functional scale designed to evaluate patients at the more moderate-severe stages of dementia when the MMSE no longer can reflect changes in a meaningful clinical way. In the early stages the patient may be able to participate in the FAST administration but usually the information should be collected from a caregiver or, in the case of nursing home care, the nursing home staff. The FAST scale has seven stages: 1 which is normal adult; 2 which is normal older adult; 3 which is early dementia; 4 which is mild dementia; 5 which is moderate dementia; 6 which is moderately severe dementia, and 7 which is severe dementia.

FAST Functional Milestones

FAST stage 1 is the normal adult with no cognitive decline. FAST stage 2 is the normal older adult with very mild memory loss. Stage 3 is early dementia. Here memory loss becomes apparent to co-workers and family. The patient may be unable to remember names of persons just introduced to them. Stage 4 is mild dementia. Persons in this stage may have difficulty with finances, counting money, and travel to new locations. Memory loss increases. The person's knowledge of current and recent events decreases. Stage 5 is moderate dementia. In this stage, the person needs more help to survive. They do not need assistance with toileting or eating, but do need help choosing clothing. The person displays increased difficulty with serial subtraction. The patient may not know the date and year or where they live. However, they do know who they are and the names of their family and friends. Stage 6 is moderately severe dementia. The person may begin to forget the names of family members or friends. The person requires more assistance with activities of daily living, such as bathing, toileting, and

eating. Patients in this stage may develop delusions, hallucinations, or obsessions. Patients show increased anxiety and may become violent. The person in this stage begins to sleep during the day and stay awake at night. Stage 6 is severe dementia. In this stage, all speech is lost. Patients lose urinary and bowel control. They lose the ability to walk. Most become bedridden and die of sepsis or pneumonia.

2/13/2008htt p://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm

Functional Assessment Staging Test (FAST)©

STAGE	SKILL LEVEL
1.	No difficulties, either subjectively or objectively.
2.	Complains of forgetting location of objects. Subjective word finding difficulties.
3.	Decreased job function evident to co-workers; Difficulty in traveling to new locations. Decreased organizational capacity.*
4.	Decreased ability to perform complex tasks (e.g., planning dinner for guests), handling personal finances (forgetting to pay bills), difficulty marketing, etc.
5.	Requires assistance in choosing proper clothing to wear for day, season, occasion.
6a.	Difficulty with putting clothing on properly without assistance.
b.	Unable to bathe properly (e.g., difficulty adjusting bath water temperature), occasionally or more frequently over the past weeks.*

c. Inability to handle mechanics of toileting (e.g., forgets to flush the toilet, does not wipe properly or properly dispose of toilet tissue) occasionally more frequently over the past weeks.*

d. Urinary incontinence, occasional or more frequent.

e. Fecal incontinence (occasional or more frequent over the past week).

7a. Ability to speak limited to approximately a half dozen different words or fewer, in a course of an average day or in the course of an intensive interview.

b. Speech ability limited to the use of a single intelligible word in an average day, or in a course of an interview (the person may repeat the word over and over).

c. Ambulatory ability lost (cannot walk without personal assistance).

d. Ability to sit up without assistance lost (e.g., the individual will fall over if there are no lateral rests [arms] on the chair).

e. Loss of the ability to smile.

STAGE: _____

*Scored primarily on the basis of information obtained from a knowledgeable informant and/or caregiver.

Reisberg, B. Functional Assessment Staging (FAST). Psychopharmacology Bulletin. 1988:24: 653-659.

INSTITUTIONAL REVIEW BOARD
RESPONSIBILITIES OF RESEARCH INVESTIGATORS

Responsibilities of Principal Investigators

The IRB holds the PI responsible for the overall management of an approved study. Management of the study encompasses the ethical, technical, administrative, and fiscal elements of a project. The PI may delegate certain tasks, but retains ultimate responsibility and accountability. Principal investigators are required to:

- Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and to understand the ethical standards and regulatory requirements governing research activities with human participants,
- Supervise all study personnel and ensure that all personnel abide by the ethical principals of respect for persons, beneficence and justice, as outlined in the Belmont Report,
- Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments),
- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,
- Report any real or potential conflicts of interests of the PI or any study personnel in compliance with conflict of interest policies and management plans,
- Obtain informed consent from participants before participants are involved in the research, and document consent as approved by the IRB. A copy of the IRB-approved informed consent document must be used. Participants must be provided with a copy of the form after it has been signed, unless the IRB has specifically waived this requirement. Documented evidence of informed consent of the participants or their legally authorized representative is to be retained in a manner approved by the IRB. The consent process involves two required elements: 1) a discussion of the study by the person obtaining consent and the participants, and 2) an opportunity for participants to read the consent form. Please note that it is never appropriate to forgo the discussion, even if participants will then read the consent form. Participants must be given the opportunity to have the consent form read to them if they have difficulty reading,
- Maintain written records of IRB reviews, decisions, research records and informed consent documents,
- Obtain IRB approval for and notify the sponsor (if applicable) of any proposed change to the research protocol *prior to* its implementation, except when necessary to eliminate apparent immediate hazards to the participants,
- Obtain re-approval by reporting progress of approved research to the IRB, in the manner prescribed by the IRB, but not less than once per year,
- Promptly report to the IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others. PIs should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without first contacting the IRB Chair, the AVPR or the ADRC in order to determine the correct course of action,
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained,

- Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained,
- Use the most current version of IRB forms and document templates, which can be downloaded from the IRB website (http://www.irb.uconn.edu/forms.html),
- Oversee the budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment supplies, storage space etc., to conduct the study at the University and any other performance site for which the PI is responsible,
- Ensure charges assessed to insurance carriers are for procedures for illness or injury directly resulting from the research procedures of the study, if applicable,
- Provide the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency,
- Communicate, when applicable, the investigator's plans to meet with representatives of the community from which individuals will be recruited, about community concerns, values and expectations,
- Maintain, when applicable, accurate records on the receipt, use and disposition of excess drugs/devices,
- Conduct the study in compliance with internal policies and regulations including 45 CFR 46 and 21 CFR 50 – Protection of Human Participants, 21 CFR 312 – Investigational New Drug Application and 21 CFR 812 – Investigational Device Exemptions; with Good Clinical Practices and, when applicable, 21 CFR 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs and 21 CFR 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals.

Responsibilities of All Key Personnel

The IRB holds all study personnel (including PI and co-investigators) responsible for meeting certain obligations. Study personnel are required to:

- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and understand the ethical standards and regulatory requirements governing research activities with human participants,
- Comply with applicable IRB policies and procedures,
- Document contact with participants, e.g., obtaining informed consent or informing participants of changes that may affect their willingness to continue participating,
- Provide a thorough explanation of the study in lay terms to the participant during the consent process,
- Provide the participant with an opportunity to ask questions and have them answered when obtaining informed consent and throughout their participation,
- Understand the appropriate use of an investigational intervention (drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors, if applicable,
- Be familiar with and follow the adverse event and protocol deviation reporting requirements.